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EXAMINER	
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ART UNIT	PAPER NUMBER
1656	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,305	KEREK, FRANZ	
	Examiner	Art Unit	
	SAMUEL W. LIU	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 33-47* is/are pending in the application.

4a) Of the above claim(s) *4-6,8,9,33-38 and 43-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7 and 39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 June 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the claims

Claims 1-9 and 33-47 are pending.

The amendment filed 2/27/09 which amends claims 1-3 has been entered. Claims 10-32 were canceled by the amendment filed 3/24/08. Claims 4-6, 8-9, 33-38 and 43-47 remain withdrawn from further consideration. Claims 1-3, 7 and 39-42 are examined in this Office action.

Withdrawal of the objection and rejections

- The objection to the specification is withdrawn in light of the amendment of the specification thereof.
- The 102 rejection of claims 1, 39 and 41 by Curtis et al. is withdrawn in light of the amendment of claim 1.
- The 103 rejection of claim 1 by Andresen at al. is withdrawn in light of the amendment of claim 1.

New-Objection to claim

In claim 2, the last line, "is" should be changed to "are" in light of "and/or".

New-Rejections under 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 7, and 39-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement; this is a new matter rejection. The claims

contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The first "structure" and second "structure" (reads on NONE of the generic formulas disclosed in pages 9-11, 16 and 23 in the specification filed 6/20/5) set forth in claim 1, which as amended into the claim on 2/27/09, are not supported by the specification as originally filed. Applicant can either cancel the new matter or point out specification support for the phrase in the specification as originally filed.

New-Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-3, 7 and 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (the last two lines) recites "amino acid C at positions 3 and 41"; the recitation is indefinites because as depicted the 41st residue of the second "structure" of the peptide (consisting of 46 amino acid residues) is NOT "C" (Cys) but "X" (undefined amino acid). Claims 3, 7 and 39-42 which depend from claim 1 are also rejected.

Claim 2 is indefinite in the recitations: (i) "at position 27 the amino acid Q"; and (ii) "at position 34 the amino acid H", because (i) the amino acid residue 27 is C (Cys) but not "Q" (Gln), and (ii) the amino acid residue 34 in the second "structure" is "I" (Ile) but not "H" (His).

The amino acid sequence of SEQ ID NO:8 (hellethionin-C) set forth in claim 3 neither reads on the first "structure" nor the second "structure" set forth in claim 1; this renders claim 3

indefinite because said "SEQ ID NO:8" of claim 3 lacks antecedent in claim 1 from which claim 3 depends.

New-Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Scope enablement

Claims 1-2, 7 and 39-42 remain rejected under 35 U.S.C. 112, first paragraph, because while the specification appears to enable the isolated cysteine–containing peptide set forth in claim 3 such as hellethionin-A (HT-A) and hellethionin-C (HT-C) (see [0054]), does not reasonably provide enablement for the peptides having generic peptide formulas, i.e., the first "structure" (S-I) and the second "structure" (S-II) set forth in claim 1, and the pharmaceutical composition comparing the peptides thereof (claims 39-42). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in *Ex parte Forman*, 230 USPQ 546(BPAI 1986). They include the nature of the invention, the state of the art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed.

(1) The scope of the claims/(2)The nature of the invention:

The instant invention is directed to the isolated bioactive cysteine-containing peptides. While the specification teaches that the peptides (SEQ ID NOs: 1-11 which are recited in claim 3) having definitive amino acid sequences have biological activities, e.g., the peptide of SEQ ID NO:1 (HT-A) has effect on inhibiting the production of several pro-inflammatory cytokines (Example 3), the peptide of SEQ ID NO:8 (HT-C) has effect on inhibiting proliferation of cancer cell line MCF-7 (Example 4), instant specification fails to teach biological function of the generic peptide formulas of i.e., the first "structure" (**S-I**) and the second "structure" (**S-II**) set forth in claim 1. Neither the specification nor the art in the relative field teaches that, when "X" (any amino acid) is cysteine residue, the peptide thereof has said biological activities as discussed above. Introducing excess of cysteine residues into the peptide would cause said peptide aggregate which is generally an inactive form; e.g., introducing a cysteine into to cysteine-containing polypeptide angiopoietin-1 (Ang1) results in polypeptide aggregation and loss of bioactivity such as activation of its receptor Tie2 (see abstract, Kim et al. (2005) *J. Biol. Chem.*, 280, 20126-20131). In this case, the scope of the claims is outside the realm of routine experimentation and would have resulted in the necessity of undue experimentation.

(3) The unpredictability of the art:

In instant peptide, "X" can be any amino acid including cysteine. Kim et al. teach the polypeptide aggregation and inactivation caused by introducing cysteine into the polypeptide thereof (see above). This indicates that when "X" is cysteine, instant peptide may aggregate or/and mis-linked intra-molecular disulfide linkages due to formation incorrect disulfide between the "introduced cysteine" and intrinsic cysteine which participates in normal intra-molecular disulfide formation (see the two "structures" of the claimed peptide set forth in instant claim 1).

Moreover, the relative art teaches that protein functionality of substitutions of non-cysteine amino acid residues in a protein (cysteine rich) is unpredictable (see the Comeglio et al. reference cited in the Office action mailed 12/2/08). These suggest that the unpredictability of the art is high.

(4) The state of the prior art:

The general knowledge and level of skilled in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Because the art does not teach or provide guidance as to construct mutants or variants which has the generic structural features set forth in claim 1 and possesses the above-discussed biological activity. The relative art (Comeglio et al.) teach unpredictability of functionality of the cysteine rich proteins resulted from mutagenesis. The specification needs to provide sufficient guidance to be considered enabling for the claimed peptides and the pharmaceutical composition comprising the peptides thereof (claims 39-42).

(5) The quantity of experimentation necessary:

In the absence of working examples with regard to the genus stated above, unpredictability of the art, the lack of sufficient guidance in the specification and the breadth of the claims, and in absence of teaching regarding core or consensus motifs or sequences (except conserved cysteine residues), it would take undue trials and errors to practice the claimed invention. The quantity of experimentation is large and not routine. One skilled in the art would have been required to carry out an undue experimentation for screening for and characterizing various polysaccharides with the structural feature discussed above for their capability of treating diverse autoimmune disease mentioned above.

(6) The relative skill of those in the art:

The general knowledge and level of skill in the art do not supplement the omitted description with respect to a massive number of variant sequences of polypeptide and broad scope of disorders encompassed by the claims. In view of the preceding factors (1-5), the level of skill in this art is high and requires at least a molecular biologist with several years of experience in peptide chemistry, pharmacology/immunology as well as knowledge in oncology and medicine. Yet, even with a level of skill in the art as those mentioned in precedence, predictability of the results is still highly variable.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view of the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention. Thus, the amount and level of experimentation needed is undue.

Applicants' response to the 112/1 rejection

At pages 11-12, the response filed 2/29/09 argues that the amendment of claim 1 would obviate the 112/1 (scope enablement) rejection. This is found unpersuasive because, as discussed above, the scope of the claims is outside the realm of routine experimentation and would have resulted in the necessity of undue experimentation. Thus, the 112/1 rejection above is proper and stands.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Samuel W Liu/
Examiner, Art Unit 1656
May 5, 2009

/Andrew Wang/
Supervisory Patent Examiner, Art Unit 1656